



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

FEE

DP BARCODE No.: 422308; **FILE SYMBOL No.:** 2517-RTE; **PRODUCT NAME:** Sergeants Bifenthrin + Nylar with Oatmeal Shampoo for Dogs; **DECISION No.:** 492111; **PC Code(s):** 128825, 129032; **ACTION CODE:** R300; **FOOD Use:** No

DATE OUT: August 29, 2014

SUBJECT: End Use Product Chemistry Review
Product Name: Sergeants Bifenthrin + Nylar with Oatmeal Shampoo for Dogs

FROM: Shyam Mathur, Ph. D
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

S Mathur 8/29/14
SCR

TO: Carlyn Petrella / Richard Gebken, RM 10
Insecticide Branch / RD (7505P)

Company Name: Sergeant's Pet Care Products Incorporation
Formulation Type: Insecticide

INTRODUCTION:

The registrant has submitted an application to register the new end use product Sergeants Bifenthrin + Nylar with Oatmeal Shampoo for Dogs. The registrant has submitted a CSF's for basic formulation & alternate formulation #1 (both dated June 9, 2014). The supporting product chemistry data have been submitted with MRID No. 49390601 to 49390603. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 2517-138. TRB has been asked to determine the acceptability of the proposed basic CSF and the supporting product chemistry data and also determine similarity to the cited product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Bifenthrin (0.05%) and Pyriproxyfen (0.015%)
2. Has the registrant claimed substantial similarity to a registered product?

☒ Yes; ☐ No; ☐ NA; if yes, give the registration number of the cited product.

Reg. No. 2517-138

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3. All of the source materials of the active ingredient are derived from registered sources: ☒ Yes ☐ No

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled Uses: ☒ Yes; ☐ No

5. Confidential Statement of Formula(s):

☒ Proposed Basic - Dated: 06-09-2014; Resubmitted – Dated:

☒ Proposed Alternate CSF #1 – Dated: 06-09-2014 ; Resubmitted – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☒ Yes; ☐ No; ☐ NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA;

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA

Methanol at > 4%: ☐ Yes ☐ No ☒ NA

Sodium nitrate/Sodium Nitrite ☐ Yes ☐ No ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown?

☒ Yes; ☐ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

d. Label requires an additional Storage and Disposal statement:

☐ Yes; ☒ No; if yes explain below:

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7. Group A: Product Chemistry Data

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos. Cited
			Yes	No		
830.1550	Product Identity & Composition		X		A	49390601
830.1600	Description of materials used to produce the product		X		A	49390601
830.1650	Description of formulation process		X		A	49390601
830.1670	Discussion on the formation of impurities		X		A	49390601
830.1700	Preliminary analysis					49390601
830.1750	Certified limits (158.350)	Standard certified limits	X			Basic CSF (06-09-2014)
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		cited		Cited	48122205 HPL-UV/235 nm. Validation reported

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA = Not applicable, I = In progress; U = Upgradeable.

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8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid	A	49390602
830.6314	Oxidation/reduction	Not expected to be oxidized nor reduced based on the chemical structures of the constituents. Therefore this data requirement is not triggered.	NA	49390602
830.6315	Flammability	Does not contain any ingredients that are considered flammable. Therefore this data requirement is not triggered.	NA	49390602
830.6316	Explosibility	Does not contain any ingredients that are considered explosible. Therefore this data requirement is not triggered.	NA	49390602
830.6317	Storage stability	In progress. Will be submitted on completion	I	49390602
830.6320	Corrosion characteristics	In progress. Will be submitted on completion	I	49390602
830.7000	pH	6.60	A	49390602
830.7100	Viscosity	4670.05 +/- 1.03 (20°C) 85.9 +/- 0.50 (40°C)	A	49390602
830.7300	Density	0.986 g/ml @ 20°C	A	49390602

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C. CONCLUSIONS:

The TRB has reviewed the proposed basic & alternate CSF's and the supporting product chemistry data for the new end use product and has concluded:

1. The proposed CSF's for basic & alternate formulations #1 (both dated 06-09-2014) are acceptable.
2. The product chemistry data submitted corresponding to the guideline 830 series group A is acceptable. See item #1.
3. The product chemistry data submitted for group B are acceptable. The registrant indicated that the studies for the guideline 830.6317 (1year storage stability) and 830.6320 (1 year corrosion characteristics) are in progress and the results will be submitted on completion. The cited validated enforcement analytical method is acceptable.
4. The proposed product with File Symbol No. 2517-RTE was determined to be substantially similar to the cited product with Reg. No. 2517-138 from the product chemistry point of view. The proposed product contains few additional ingredients in minor quantities and will not significantly change the properties of the proposed product. These ingredients are not present in the cited product.

